



Uniform Formulary Medical Necessity Criteria for Attention Deficit Hyperactivity Disorder (ADHD) Agents

Drug Class - Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy Agents. This drug class includes agents primarily used to treat ADHD, some of which have FDA indications for narcolepsy, as well as two agents that are indicated for the treatment of narcolepsy, but not ADHD.

Background - After evaluating the relative clinical and cost effectiveness of the ADHD and narcolepsy agents, the DoD P&T Committee recommended that the following medications be designated as non-formulary. All of these medications are primarily used for ADHD. This recommendation has been approved by the Director, TMA.

Effective Date: 18 April 2007

- Daytrana (methylphenidate patch)
- Focalin (dexmethylphenidate immediate release)
- Focalin XR (dexmethylphenidate extended release)

Effective Date: 16 April 2008

- Vyvanse (lisdexamfetamine)

Patients or parents of patients currently using a nonformulary ADHD agent may wish to ask their doctor to consider a formulary alternative.

Uniform Formulary Status, Copays, and Therapeutic Alternatives for ADHD Agents *, **

Uniform Formulary Status	Medication	MTF (up to a 90 day supply)	TMOP (up to a 90 day supply)	Retail (up to a 30-day supply)
Non-Formulary (Tier 3)	ADHD agents Focalin, Focalin XR, Daytrana, Vyvanse	Not available**	\$22	\$22
Formulary (Tier 2)	<i>ADHD agents***</i> Adderal XR, Concerta, Metadate CD, Ritalin LA, Strattera <i>Narcolepsy agents</i> Provigil, Xyrem	\$0	\$9	\$9
Formulary (Tier 1)	<i>ADHD agents***</i> Dexamphetamine IR, mixed amphetamine salts IR, methamphetamine IR, methylphenidate IR and SR	\$0	\$3	\$3
IR = immediate release; SR = sustained release * Active duty copay always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary. ** MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-				

MTF provider to whom the patient was referred, as long as medical necessity has been established.

*** ADHD agents may be divided into two general groups: 1) stimulants (which include both amphetamine products such as Adderall XR and Vyvanse, and methylphenidate products such as Concerta, Metadate CD, and Ritalin LA) and 2) the non-stimulant atomoxetine (Strattera). Extended release formulations of the stimulants are most commonly used, with immediate release formulations reserved for dose titration or for augmenting treatment during specific time periods. In most cases, Focalin (dexmethylphenidate immediate release) would not be used as a sole therapy; therefore, medical necessity review is based on extended release products only. Strattera is less commonly used than the stimulants and is often reserved for specific patient groups (e.g., patients who cannot tolerate the adverse effects of stimulants).

Accordingly, therapeutic alternatives to dexmethylphenidate (Focalin, Focalin XR), methylphenidate patch (Daytrana), and lisdexamfetamine (Vyvanse) are considered to be the formulary extended release stimulant products: extended release methylphenidate (e.g., Concerta, Metadate CD, Ritalin LA) and extended release mixed amphetamine salts, (Adderall XR).

Medical Necessity Criteria

The \$22 non-formulary copay for Daytrana (methylphenidate patch), Focalin (dexmethylphenidate immediate release), Focalin XR (dexmethylphenidate extended release), or Vyvanse (lisdexamfetamine) may be reduced to the \$9 formulary copay if the patient meets any of the following criteria. Note: approved medical necessity determinations for dexmethylphenidate products will apply to both Focalin and Focalin XR.

1. Use of ALL of the following formulary alternatives is contraindicated (e.g., due to hypersensitivity): extended release methylphenidate (e.g., Concerta, Metadate CD, and Ritalin LA) and extended release mixed amphetamine salts (Adderall XR).
2. The patient has experienced or is likely to experience significant adverse effects from ALL of the following formulary alternatives: extended release methylphenidate (e.g., Concerta, Metadate CD, and Ritalin LA) and extended release mixed amphetamine salts (Adderall XR).
3. Use of ALL of the following formulary alternatives has resulted in therapeutic failure: extended release methylphenidate (e.g., Concerta, Metadate CD, and Ritalin LA) and extended release mixed amphetamine salts (Adderall XR).
4. (Daytrana patch only) - The patient is unable to take oral medications.

Medical necessity criteria for Daytrana, Focalin, and Focalin XR recommended by the DoD Pharmacy & Therapeutics Committee at the Nov 2006 meeting & approved by the Director, TMA on 17 Jan 2007. Medical necessity criteria for Vyvanse recommended by the DoD Pharmacy & Therapeutics Committee at the Nov 2007 meeting & approved by the Director, TMA on 13 February 2008. For more information, please see the [DoD P&T Committee minutes](#) for these meetings.

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